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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,932	01/09/2006	Mark G. Erlander	14255-052US1	7099

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
10/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/507,932	ERLANDER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Applicants' response to the office action field on June 08, 2009 has been considered and acknowledged.

Status of the application and response to Arguments

2. Currently claims 2-38 are pending. Claim 1 was previously cancelled. Applicants' arguments have been fully considered and deemed persuasive. The rejections that are not reiterated are withdrawn herein in view of the persuasive arguments.

Information Disclosure Statement

3. The Information Disclosure Statement filed on July 30, 2009 has been considered and acknowledged.

Non-Statutory Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6, 794,141 (hereafter '141). An obviousness-type double patenting rejection is appropriate where

the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim 2, and 21 are generic to all that is recited in claims 1, 6, 10, 17, and 23 of the patent '141 . That is, the claims 1, 6, 10, 17, and 23 of the patent '141 fall entirely within the scope of claims 2 and 21, or in other words, claims 2 and 21 are anticipated by the claims1, 6, 10, 17, and 23 of the patent '141. Specifically a method for producing amplified RNA (aRNA) comprising (a) reverse transcribing an RNA template using a promoter-primer complex and an RNA dependent DNA polymerase (reverse transcriptase enzyme) to produce a first strand cDNA ;(b) treating the reverse transcription product with RNAse H enzymatic activity; (c) producing a second strand cDNA complementary to said first strand cDNA using a DNA dependent polymerase, in the presence of random primers to prime the synthesis of said second strand cDNA; (d) producing amplified RNA from the eluted double stranded cDNA by in vitro transcription using a DNA dependent RNA polymerase which initiates transcription from the promoter-primer complex, wherein the product produced after c), after d) or both, is purified by contacting said product with a solid phase which binds nucleic acids followed by eluting bound nucleic acids from the solid phase is within the scope of the instant claims 2 and 21. Further, claims 3-20, 22-38 are generic to all that is recited in claims 2-5, 7-9, 11-16, 18-22, 24-32 of the patent '141. The only obvious variation is that the

instant claims recite incubation periods of first and second strand synthesis, which is fully supported by the disclosure of the patent '141 (see at least col. 15, line 56-67, col. 16, 1-12), which is considered as an obvious variation. Thus the instant claims encompass the claims in the patent ('141) and are related as genus and species, and are coextensive in scope.

The courts have stated that a genus is obvious in view of the teachings of a species. see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir. 1989). Therefore the instantly claimed method is obvious over the claims in the patent. Thus the instant claims are rejected under obviousness-type of double patenting.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziman et al. (US 2004/0081978A1) in view of Godfrey et al. (US 7,101,663).

Ziman et al. teach a method of claim 2, 9-10, 20, 28-29, 38, for producing amplified RNA (aRNA) comprising

(a) reverse transcribing an RNA template using a promoter-primer complex and an RNA dependent DNA polymerase (reverse transcriptase enzyme) to produce a first strand cDNA (see page 5, paragraph 0041-0042, 0035-0036, page 6, paragraph 0048)

(b) treating the reverse transcription product with RNAse H enzymatic activity (see page 5, paragraph 0040, page 6, paragraph 0048);

(c) producing a second strand cDNA complementary to said first strand cDNA using a DNA dependent polymerase, in the presence of random primers to prime the synthesis of said second strand cDNA (see page 5, paragraph 0043-0045);

(d) producing amplified RNA from the eluted double stranded cDNA by in vitro transcription using a DNA dependent RNA polymerase which initiates transcription from the promoter-primer complex (see page 6, paragraph 0050-0056);

wherein the product produced after c), after d) or both, is purified by contacting said product with a solid phase (Qiagen column) which binds nucleic acids followed by eluting bound nucleic acids from the solid phase dissolved in less than 50 ul (see page 9, paragraph 0084).

With regard to claims 3-4, Ziman et al. teach that the RNA template comprises mRNA and the template is derived from cellular mRNA preparation (see page 10, paragraph 0089-0096).

With regard to claims 5-6, Ziman et al. teach that the first primer comprises oligo d(T) comprising at least 8 dT (see page 4, paragraph 0032-0034, page 5, paragraph 0035).

With regard to claim 7-8, 23-24, Ziman et al. that the random primers are six to 10 nucleotides (see page 5, paragraph 0044-45).

With regard to claims 11, 22, 25-27, Ziman et al. teach that the promoter primer comprises T7 or T3 promoter sequence and second primer comprises a known sequence complementary to the 3'region of said amplified RNA (see page 6, paragraph 0052-00554).

With regard to claims 12-19, 30-37, Ziman et al. teach use of silica particles to purify the first or the second cDNA product, said purification involves centrifugation at high speed without the use of a vacuum (see page 9, paragraph 0084).

However Ziman et al. did not specifically teach completion of each of the first and second cDNA synthesis steps in less than 45 minutes.

Godfrey et al. teach rapid RT-PCR method which is performed in less than 10 minutes (see col. 2, line 62-67, col. 3, line 1-3).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of producing aRNA as taught by Ziman et al. with a step of completing the method steps in less than 45 minutes as taught by Godfrey et al. to achieve expected advantage of developing a sensitive and enhanced method of producing aRNA. An ordinary practitioner would have been motivated to

combine the teaching of Ziman et al. with the step of completing the reaction in less time as taught by Godfrey et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in a rapid, automated method for RT-PCR (see col. 2, line 62-67, col. 3, line 1-3) and such modification of the method would be considered as obvious over cited prior art. Further, as noted in *In re Aller*, 105 USPQ 233 at 235,More particularly, where the general conditions (suitable volume, incubation time) of a claim are disclosed in the prior art (Ziman et al. and Godfrey et al.), it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of hybridization conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637